

## Section 6- 510(k) Summary of Safety and Effectiveness

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**6.1 Statement** This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of **SMDA 1990** and **CFR 807.92**

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**6.4 Device Name** **Proprietary Name:** Haemonetics LN994CF-BA Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter, and 4ml Sampling System.

**Common Name:** Platelet and Plasma collection set, apheresis

**Classification Name:** Empty Processing Container for the collection and processing of blood and blood components

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**6.5 Predicate Legally Marketed Devices** The modified device, the Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter, and 4ml Sampling System (LN994CF-BA) is substantially equivalent to the Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter (LN994CF). The predicate device was most recently reviewed and cleared via the premarket notification process as part of **BK010035**

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**6.6  
Device  
Description**

The Haemonetics extended storage platelet and plasma set, with Saline Compensation, PALL filter, and 4ml sampling port is a device used of the collection of platelets derived from apheresis using the MCS+ LN9000.

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**6.7  
Device  
Indications and  
Intended use**

The Haemonetics extended Storage Platelet and Plasma Set with Saline Compensation, PALL filter (LRF-XL), and 4ml sampling system is intended to be used to collect one unit of platelets, leukocyte reduced (with or without plasma). Additionally, the set may be used to collect two units of platelets, leukocyte reduced. The attached Haemonetics 4ml sampling system is intended to be used *to* obtain a sample of the platelets collected that is greater of equal to 4 milliliters.

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Table of Substantial Equivalence		
List Number	LN 994CF	LN994CF-BA
Device Name	Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter	Extended Storage Platelet and Plasma Apheresis Set with Leukocyte Reduction Filter, and 4ml Sampling System.
Intended use	The Haemonetics extended Storage Platelet and Plasma Set with Saline Compensation, PALL filter (LRF-XL), and 4ml sampling system is intended to be used to collect one unit of platelets, leukocyte reduced (with or without plasma). Additionally, the set may be used to collect two units of platelets, leukocyte reduced.	The Haemonetics extended Storage Platelet and Plasma Set with Saline Compensation, PALL filter (LRF-XL), and 4ml sampling system is intended to be used to collect one unit of platelets, leukocyte reduced (with or without plasma). Additionally, the set may be used to collect two units of platelets, leukocyte reduced. The attached Haemonetics 4ml sampling system is intended to be used to obtain a sample of the platelets collected that is greater or equal to 4 milliliters.
Materials	Various Plastics, PVC Tubing	Various Plastics, PVC Tubing,
Sterilization/ Labeling	Ethylene Oxide, Sterile, Single Use	Ethylene Oxide, Sterile Single Use
Associated Equipment	Haemonetics MCS+ LN9000	Haemonetics MCS+ LN9000

Applicant: *Ans I*

Date — 3/2/07